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Intravitreal triamcinolone versus laser photocoagulation for diabetic macular oedema

Submission date	Recruitment status	[_] Prospectively registered
10/02/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/04/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/12/2020	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Study information

Scientific Title
Intravitreal triamcinolone versus laser photocoagulation as a primary treatment for diabetic macular oedema: a comparative pilot study

Study objectives

To assess whether intravitreal triamcinolone produced a better outcome compared to laser photocoagulation as a primary treatment for diabetic macular edema (DME)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research and Ethical Committee, School of Medical Sciences, Universiti Sains Malaysia, approved on the 01/08/2006 [ref: USM/PPSP®/Ethics Com./2006 176.3(1)]

Primary study design
Interventional

Study design
Randomised controlled blinded comparative pilot study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Diabetes mellitus

Interventions
All patients underwent a complete ocular and systemic assessment once they consented for the study. The assessment was performed by the primary investigator before they were randomised into the two groups.

Pre-treatment parameters measurements:
Visual acuity of both eyes was tested with the standard retro illuminated Snellen chart. BCVA for each eye was recorded in logarithm of the minimum angle of resolution (log MAR) notations and used as a baseline. Assessment of visual acuity was performed by a blinded optometrist. All patients underwent subjective refraction by one optometrist. This is important as any astigmatism of -1 Dioptre and more need to be corrected with astigmatism lens before proceeding with the HRT II for measurement of MEI.

Baseline intra-ocular pressure (IOP) of both eyes was taken using Goldmann applanation tonometry for three times and the average was taken as the IOP at baseline. Assessment of visual acuity was performed by a blinded ophthalmologist. Fundus examination was done using 78 Dioptre lens on slit lamp bio microscopy and binocular indirect ophthalmoscopy. DME was classified as mild, moderate and severe based on the International Clinical Diabetic Macular Oedema Disease Severity Scale.

MEI analysis has been incorporated within the HRT II as the macular oedema mapping (MEM). The baseline MEM was taken using the HRT II. Patients were properly positioned in front of the HRT II system with their full correction of astigmatism if any. The focus was then adjusted to get a clear image of the macula formed on the monitor. Three sets of three consecutive images were captured each time. To ensure image quality and proper handling, all guidelines recommended by the manufacturer were followed. The best image was chosen based on the quality and smallest standard deviation. One good quality scan of each eye was utilised in all analyses. A 0.5 mm diameter circle was drawn using the circle draw facility of the HRT II. The area was chosen based on the most oedematous area and the same area was marked for the follow up

photograph at three months. Measurement of MEI was performed by a blinded trained medical technician. After the baseline measurement of MEI, all the patients were randomized using the envelope technique. The type of treatment selected would be performed the next day.

Treatment procedure:
1. Laser photocoagulation:
Patients were properly positioned on a stable chair with the chin rested on the slit lamp that was mounted with a laser wavelength, Carl Zeiss Visulas 532S laser system. Patients were given grid or focal laser depending on the type of the macular oedema. Topical anaesthetic, 5% proparacaine hydrochloride was instilled in the eye which needed to be lasered. The laser settings were 50 micron spot size, duration of 0.1 seconds and appropriate power started from 50 mW and stepped up till it burned the retina with light gray burn. The number of laser burn given was based on the severity of diabetic macular oedema (range: 20 200 laser burns and 500 µm away from the centre of the fovea).Only one session of laser (either focal or grid laser) was given to each patient in LASER group. The procedure was done by Investigator A (ophthalmologist). Patient was follow-up at 3 months post laser and no other treatment was given during that period.

2. Intravitreal triamcinolone acetonide:
Intravitreal injection of triamcinolone was carried out under sterile conditions in the operation room. Patient was admitted on a day care basis. Topical chloramphenicol four times a day was prescribed one day prior to procedure. The procedure was done under local anaesthesia using topical 5% proparacaine hydrochloride. The selected eye was properly cleaned and draped. An eye speculum was then applied; flush irrigation with 5 ml 5% povidone iodine was performed on the eye for one minute.

Triamcinolone acetonide in a single-use vial (40 mg/ml, 1 ml vial), was drawn into a 1 cc tuberculin syringe after cleansing the top of the bottle with an alcohol wipe. A separate 27 gauge needle was placed onto the syringe, which was then inverted to remove air bubbles. The excess triamcinolone was discarded till 0.1 ml (4 mg) remained in the syringe.

The site of injection was then identified, at 3.5 mm in pseudophakic and 4 mm in phakic eye to ensure against passage of the needle through the vitreous base. It was given at the inferotemporal region to avoid drug deposition in front of the visual axis. Triamcinolone acetonide of 4 mg in 0.1 ml was injected into the vitreous using a 27-gauge needle transconjunctivally. Using a single, purposeful continuous manoeuvre, the 4 mg triamcinolone acetonide was injected into the eye. The needle was removed simultaneously with the application of cotton tipped applicator over its entry site to prevent regurgitation of the injected material. Indirect ophthalmoscopy was performed to check for central retinal artery pulsation. The procedure was done by Investigator B (ophthalmologist). Topical chloramphenicol four times daily would be continued for one week. Only one injection of IVTA was given to each patient in IVTA group. Patient was follow-up at 3 months post IVTA and no other treatment was given during that period.

Post-Treatment Parameters Measurements:
IOP were assessed post IVTA procedure. IOP was checked at one hour post IVTA. Raised IOP was defined as any elevation of IOP more than 2 mmHg from baseline. It was graded to Grade I for IOP = 20 34 mmHg, Grade II for IOP = 35 mmHg and Grade III = 50 mmHg. If the IOP was high, topical anti glaucoma, gutt timolol 0.5% twice daily would be prescribed. Patients were seen in one weeks time to review the IOP. If any of the patient who was on anti glaucoma, the IOP would be reviewed again at one month, if not patient would be seen at three months post treatment to assess the study outcome.

Patient was follow-up at 3 months post procedure. The similar step of visual acuity, MEI and IOP assessment as pre-treatment measurement was done. The outcome measures were mean BCVA, mean MEI mean IOP.

Ways to minimise study error:
The following steps were taken to reduce errors while conducting the study:
1. Patients were selected strictly based on the inclusion and exclusion criteria
2. Randomisation of patients
3. IVTA and laser photocoagulation were performed by experienced ophthalmologist who was masked to patient's identity. A standardised technique was used for both procedures.
4. The measurement of MEI was performed by one identified and trained medical technician
5. The primary investigator was masked to patient's identity and procedures when analysing the MEI results (pre and post intervention) of all patients

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Measured at 3 months post-procedure:
1. Best Corrected Visual Acuity (BCVA)
2. Macular oedema index

Key secondary outcome(s)
Intraocular pressure, at 3 months post-procedure

Completion date
01/02/2008

Eligibility

Key inclusion criteria
1. Diabetic patients
2. Newly diagnosed clinically as DME
3. Aged more than 18 years old
4. Eeither sex

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
40

Key exclusion criteria
1. Patients with media opacity impairing intravitreal injection or laser photocoagulation procedure
2. DME with proliferative diabetic retinopathy still undergoing pan retinal photocoagulation
3. History of ocular surgery (eg. cataract operation) or Yag procedure with the risk of further aggravating the macular oedema
4. Intra-ocular pressure greater than 25 mmHg or any established glaucoma patient
5. Ocular or systemic infection
6. Known steroid allergy or responder
7. History of systemic steroid within 4 months prior to randomisation
8. HbA1c more than 10%

Date of first enrolment
01/06/2007

Date of final enrolment
01/02/2008

Locations

Countries of recruitment
Malaysia

Study participating centre
Department of Ophthalmology
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Sponsor information

Organisation
University of Malaysia [Universiti Sains Malaysia] (Malaysia)

ROR
https://ror.org/02rgb2k63

Funder(s)

Funder type
University/education

Funder Name
University of Malaysia [Universiti Sains Malaysia] (Malaysia) (ref: 304/PPSP/6131552)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	23/11/2011		Yes	No